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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,441	03/28/2001	Thomas H. Campbell	21120-303	6655

7590 01/04/2005

OPPENHEIMER WOLFF & DONNELLY, LLP
840 Newport Center Drive
Suite 700
Newport Beach, CA 92660

EXAMINER	
MARMOR II, CHARLES ALAN	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/820,441	CAMPBELL ET AL.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6,9*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Examiner acknowledges the cancellation of claims 2, 4 and 6-24 via the Preliminary Amendment filed March 28, 2001. Claims 1, 3 and 5 are pending.

Information Disclosure Statement

2. The information disclosure statement filed March 15, 2002 has not been fully considered because it fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The Non-Patent Literature Documents cited in the IDS of March 15, 2002 are not present in the application file. The IDS has been placed in the application file, but the Non-Patent Literature Documents referred to therein have not been considered.

Specification

3. The disclosure is objected to because of the following informalities: In page 1, lines 17-18, the current status of the related U.S. patent application should be provided. Appropriate correction is required.

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

5. Claim 1 is objected to because of the following informalities:

a. In line 1, "suitable" apparently should be deleted.

b. In line 3, "suitable" apparently should read --adapted-- or --configured--.

c. In line 5, "suitable" apparently should be deleted.

d. In line 8, "suitable" apparently should be deleted.

Appropriate correction is requested.

6. Claim 3 is objected to because of the following informalities:

a. In line 3, "suitable" apparently should read --adapted-- or --configured--.

b. In line 5, "suitable" apparently should be deleted.

c. In line 7, "suitable" apparently should be deleted.

Appropriate correction is requested.

7. Claim 5 is objected to because of the following informalities:

a. In line 3, "suitable" apparently should read --adapted-- or --configured--.

b. In line 5, "suitable" apparently should be deleted.

c. In line 9, "suitable" apparently should be deleted.

d. In line 10, "suitable" apparently should be deleted.

Appropriate correction is requested.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Inconsistent terminology used to define a claim limitation renders the claim indefinite. Specifically, the limitation "the infusion port being positioned between..." at line 11 renders the claim indefinite. It is unclear whether the tool has only one infusion port as the limitation at line 11 implies, or if there can be more infusion ports as indicated by the limitation "at least one infusion port" at line 10 of the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Nichols et al. ('708). Nichols et al. teach a combined thermal mapping and agent delivery tool. The tool includes an

elongated member **10** for insertion into a body vessel; a plurality of thermal sensors **61** suitable for detecting the temperature of a wall of the vessel; and at least one infusion port **42** is provided for delivering an agent into the vessel (see Fig. 9).

12. Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Tachibana et al. ('842). Tachibana et al. teach an interventional combined thermal mapping and agent delivery tool. The tool **10** includes an elongated member for insertion into a body vessel. An expansion device **12,30** is carried by the elongated member. A multiplicity of thermal sensors **22** suitable for detecting the temperature of a wall of the vessel are disposed on the expansion device. An outer sheath or coating may be positioned over the thermal sensors. At least one infusion port **26,26A** is provided for delivering an agent into the vessel in the region of the thermal sensors.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claim 3 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 18 of U.S. Patent No. 5,924,997. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the instant application is merely broader than the claim of the patent. Claim 18 of the patent recites a thermal mapping catheter having an elongated member for insertion into a body vessel, a plurality of thermal sensors, a plurality of infusion ports for delivering agents, and several other elements. The catheter of the patent claim is a type of "tool" as claimed in claim 3 of the instant application. Since the narrower claim of the patent "anticipates" the broader claim of the instant application, the claims are not patentably distinct.

15. Claims 1, 3 and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3 and 5 of U.S. Patent No. 6,245,026. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader than the claims of the patent. Regarding claim 1 of the application, claim 1 of the patent recites an elongated member, a plurality of thermal sensors, an expansion device and a sheath/member covering the thermal sensors, as well as additional limitations not claimed in claim 1 of the application. Regarding claim 3 of the application, claim 3 of the patent recites an elongated member, a plurality of thermal sensors, and at least one infusion port, as well as additional limitations not claimed in claim 3 of the application. Regarding claim 5 of the application, claim 5 of the patent recites an elongated member, a plurality of longitudinally spaced thermal sensors, an expansion device and at least one infusion port positioned between selected thermal sensors, as well as additional

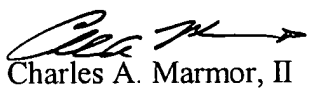
limitations not claimed in claim 5 of the application. Since the narrower claims of the patent "anticipates" the broader claims of the instant application, the claims are not patentably distinct.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

cam
July 26, 2004

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	6

Complete if Known	
Application Number	09/820441
Filing Date	March 28, 2001
First Named Inventor	Campbell et al.
Group Art Unit	3736
Examiner Name	Unknown
Attorney Docket Number	21120.303

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	U.S. Patent Document Number	Date of Publications of Cited Documents MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
cp		RE 32204	07/15/1986	Halvorsen	
		3273395	09/20/1966	Schwarz	
		3638640	02/01/1972	Shaw	
		3866599	02/18/1975	Johnson	
		3913568	10/21/1975	Carpenter	
		4005605	02/01/1977	Michael	
		4200110	04/29/1980	Peterson et al.	
		4281645	08/04/1981	Jöbsis	
		4602642	07/29/1986	O'Hara et al.	
		4699147	10/13/1987	Chilson et al.	
		4752141	06/21/1988	Sun et al.	
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		4790324	12/13/1988	O'Hara et al.	
		4794931	01/03/1989	Yock	
		4797840	01/10/1989	Fraden	
		4799479	01/24/1989	Spears	
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		4841981	06/27/1989	Tanabe et al.	
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		5197470	03/30/1993	Helfer et al.	
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		5237996	08/24/1993	Waldman et al.	
cp		5275594	01/04/1994	Baker et al.	

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Examiner Signature	Pamela Wood Charles Marmor II	Date Considered	11.17.02 7/26/04

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Application Number	09/820441
Filing Date	March 28, 2001
First Named Inventor	Campbell et al.
Group Art Unit	3736
Examiner Name	Unknown
Attorney Docket Number	21120.303

		5279565	01/18/1994	Klein et al.	
		5282813	02/01/1994	Redha	
		5293872	03/15/1994	Alfano	
		5304173	04/19/1994	Kittrell et al.	
		5313949	05/24/1994	Yock	
		5336178	08/09/1994	Kaplan et al	
		5355880	10/18/1994	Thomas et al.	
		5373849	12/20/1994	Maroney et al.	
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		5445157	08/29/1995	Adachi et al	
		5453448	09/26/1995	Narciso, Jr.	
		5496271	03/05/1996	Burton et al.	
		5496311	03/05/1996	Abele et al.	
		5542915	08/06/1996	Edwards et al	
		5542928	08/06/1996	Evans et al.	
		5547472	08/20/1996	Onishi et al	
		5558093	09/24/1996	Pomeranz	
		5582170	12/10/1996	Soller	
		5596995	01/28/1997	Sherman et al.	
		5606974	03/04/1997	Castellano et al	
		5611338	03/18/1997	Gallup et al.	
		5620438	04/15/1997	Amplatz et al.	
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		5682899	11/04/1997	Nashef et al	
		5708275	01/13/1998	Rhodes	
		5733739	03/31/1998	Zakim et al	
		5792050	08/11/1998	Alam et al.	
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		5865788	02/02/1999	Edwards et al.	
		5871449	02/16/1999	Brown	
		5906636	05/25/1999	Casscells, III et al.	
		5910101	06/08/1999	Andrews et al.	
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		6084174	07/04/2000	Hedengren et al.	
		6245026	06/12/2001	Campbell et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5]	Name of Patentee or Applicant of Cited Document	Date of Publications of Cited Documents MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		GR	649410			01/07/1976		N
		WO	8911311	A1	Kasevich	11/30/1989		
		WO	9415529	A1	Konings	07/21/1994		
		WO	9502362	A1	Milo	01/26/1995		
		WO	9710748	A1	Casscells et al	03/27/1997		
		WO	0027278	A1	Campbell et al.	05/18/2000		
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		EP	0856278	A2	Brown	8/5/1998		
		EP	0392897	A3	Sun	10/17/1990		
		EP	0570239	A1	Cross et al.	11/18/1993		

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
—		Alam et al;. Characterization of pH Variation in Lysed Blood by Near-Infrared Spectroscopy; Appl. Spectroscopy; 52:393-399 (1998)	
—		Belli et al.; Influence of Temperature on the Radiation Response of Mammalian Cells in Tissue Culture, Radiation Research, 18, 272-276 (1963)	
—		Bellocq et al.; Low Environmental pH Is Responsible for the Induction of Nitric-oxide Synthase in Macrophages; J. Biol Chem 273:5086-5092 (1998)	
—		Berliner et al.; Atherosclerosis: Basic Mechanisms – Oxidation, Inflammation, and Genetics, Circulation, vol. 91, No. 9, May 1, 1995, pp. 2488-2496	
—		Biffl et al.; Interleukin-6 Delays Neutrophil Apoptosis, Arch Surg/Vol 131, January 1996, pp. 24-30	
—		Blackburn et al.; The Sensitivity to Hyperthermia of Human Granulocyte/Macrophage Progenitor Cells (CFU-GM) Derived from Blood or Marrow of Normal Subjects and Patients with Chronic Granulocytic Leukemia, Br. J. Cancer (1984), 50, 745-751	
—		Buja et al.; Role of Inflammation in Coronary Plaque Disruption, pp. 503-505, Circulation, Vol. 89, No. 1, January 1994	
—		Carney et al.; Near-Infrared Spectrophotometric Monitoring of Stroke Related Changes in the Protein and Lipid Composition of Whole Gerbil Brains; Anal Chem 65:1305-13 (1993)	

Examiner Signature	Charles Marmor, II	Date Considered	7/26/04

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Filing Date	March 28, 2001
First Named Inventor	Campbell et al.
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Examiner Name	Unknown
Attorney Docket Number	21120.303

—		Casscells et al; Thermal Detection of Cellular Infiltrates In Living Atherosclerotic Plaques: Possible Implications for Plaque Rupture and Thrombosis, pp. 1447-1449 and 1422, The Lancet, Vol. 347, May 25, 1996	
—		Cassis et al; Near-IR Imaging of Atheromas in Living Arterial Tissue; Ana. Chem 65:1247-56 (1993)	
—		Chen et al.; Induction of Prostaglandin Production by Hyperthermia in Murine Peritoneal Exudate Macrophages, Cancer Research 47, 11-15, January 1, 1987.	
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Examiner Signature	Charles Marmor, II	Date Considered	7/26/04

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Sheet 5 of 6

Complete if Known	
Application Number	09/820441
Filing Date	March 28, 2001
First Named Inventor	Campbell et al.
Group Art Unit	3736
Examiner Name	Unknown
Attorney Docket Number	21120.303

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Examiner Signature	Charles Marmor, II	Date Considered	7/26/04

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Sheet	6	of	6

Complete if Known	
Application Number	09/820441
Filing Date	March 28, 2001
First Named Inventor	Campbell et al.
Group Art Unit	3736
Examiner Name	Unknown
Attorney Docket Number	21120.303

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Examiner Signature	Charles Marmor, II	Date Considered	7/26/04

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Sheet 1 of

Complete if Known	
Application Number	09/820,441
Filing Date	03/28/2001
First Named Inventor	Campbell
Group Art Unit	3736
Examiner Name	Unknown
Attorney Docket Number	21120-303

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	U.S. Patent Document Number	Date of Publications of Cited Documents MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
CP	AA	5,792,070	08-11-1998	Kauphusman et al.	Claims 1-24
CP	AB	6,245,026	06-12-2001	Campbell et al.	Claims 3, 11-13, 19, 20, 23

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Notice of References Cited	Application/Control No. 09/820,441	Applicant(s)/Patent Under Re xamination CAMPBELL ET AL.	
	Examiner Charles A. Marmor, II	Art Unit 3736	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,433,708 A	07-1995	Nichols et al.	604/113
	B	US-6,176,842 A	01-2001	Tachibana et al.	604/22
	C	US-			
	D	US-			
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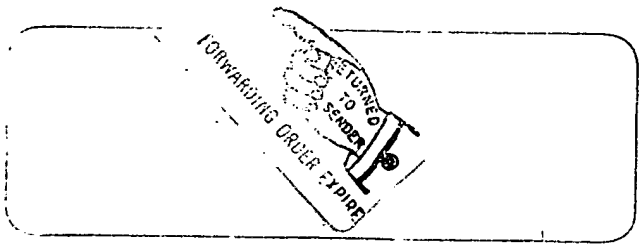
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